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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,439	04/22/2005	Leslie Joe Dunaway	S-0828-A-US	9140
2071 7590 03/10/2011 McGLINCHEY STAFFORD, PLLC Attn: IP Group 301 Main Street, 14th Floor BATON ROUGE, LA 70802				
EXAMINER MAEWALL, SNIGDEHA				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
03/10/2011		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/532,439

**Applicant(s)**

DUNAWAY, LESLIE JOE

**Examiner**

SNIGDHA MAEWALL

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 15-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-040)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date 09/03/10
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### Summary

1. Receipt of Applicant's arguments/Remarks, amended claims and **RCE** filed on 09/03/10 is acknowledged.

Claims 1-7 and 15-21 remain withdrawn. Claim 8 has been amended.

**Claims 8-14** are under prosecution.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 8-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "reducing" in claim 8 is a relative term which renders the claim indefinite. The term reducing is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arneric (US PG Pub. 2004/0235925 A1) by itself or in view of (applicant's own admission on page 1 of instant disclosure).

Arneric discloses a method for treating inflammation or an inflammation associated disorder in a subject in need of by providing atomoxetine and cyclooxygenase-2 selective inhibitor (see abstract).

The reference teaches treatment of inflammatory disorders such as asthma, see paragraph [0470] on page 45. The reference teaches Atomoxetine may be obtained from any source and refers to USP 4,314,081 for the preparation of atomoxetine. (Note: the reference USP 4,314,081 teaches using Atomoxetine HCl salt.). The reference teaches oral administration in [0480] on page 46. The reference teaches oral administration [0480] on page 46. The reference teaches in paragraph [0477] on page 46 that the administration of each agent that is atomoxetine and cyclooxygenase 2 inhibitor is in a **sequential** manner, can be taken together or taken within a period of time sufficient to provide beneficial effect. Prior art teaches sequential administration, it is therefore evident that atomoxetine by itself has therapeutic effect in treating disorders

related to asthma, therefore administration of atomoxetine only, to treat disorders related to asthma would be obvious to one of ordinary skill in the art. Since the prior art teaches treating asthma, one of ordinary would expect the reduced airway reactivity.

Applicants disclose in paragraph [0004] of instant disclosure that it is well known fact that asthma is associated with an increased reactivity of the airways on exposure to environmental allergens. Therefore it is implicit that one of ordinary skill would expect reduced airway activity caused during asthma once the composition of Arneric is used with atomoxetine.

**Response to Arguments/declaration**

6. Applicant's arguments filed 09/03/10 have been fully considered but they are not persuasive.

Applicant argues that in his opinion, the cited reference of Arneric would not have made the presently claimed invention apparent to such a person of ordinary skill in the art as of the filing date of this application. Such a person of ordinary skill in the art to which this invention pertains likewise would not have been motivated to attempt to employ a composition consisting essentially of atomoxetine, to treat mammalian asthma, and more particularly to treat the airway reactivity associated with asthma in a mammal, including humans.

Applicant's arguments are not persuasive. Applicant's arguments are not supported by facts or factual evidence with experimental data to overcome the rejection has not been provided by applicants. Opinion of applicants does not replace factual

evidence. Prior art teaches treatment of inflammatory disorders such as asthma by atomoxetine as discussed above. Absent evidence of unexpected results, the rejection is maintained.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/  
Examiner, Art Unit 1612  
/Gollamudi S. Kishore/  
Primary Examiner, Art Unit 1612

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